# Zai Lab and Novocure Announce Pivotal LUNAR Study in Non-Small Cell Lung Cancer Met Primary Overall Survival Endpoint

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*The LUNAR study met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival*

*The full LUNAR data will be presented at a future medical congress*

SHANGHAI and CAMBRIDGE, Mass. and ROOT, Switzerland, Jan. 05, 2023 (GLOBE NEWSWIRE) -- Zai Lab Limited (Nasdaq: ZLAB; HKEX: 9688) and Novocure (NASDAQ: NVCR) today announced the LUNAR study met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival over standard therapies alone. The LUNAR study is a pivotal, open-label, randomized study evaluating the safety and efficacy of Tumor Treating Fields (TTFields) together with standard therapies for stage 4 non-small cell lung cancer (NSCLC) following progression while on or after treatment with platinum-based therapy.

The LUNAR study also showed a statistically significant and clinically meaningful improvement in overall survival when patients were treated with TTFields and immune checkpoint inhibitors (ICI), as compared to those treated with immune checkpoint inhibitors alone, and a positive trend in overall survival when patients were treated with TTFields and docetaxel versus docetaxel alone. Patient enrollment was well balanced between the ICI and docetaxel cohorts of the experimental and control arms, and control arms performed in line with prior studies. TTFields therapy was well tolerated by patients enrolled in the experimental arm of the study.

“We are pleased with the positive readout of the LUNAR study. Prior to LUNAR, the last phase 3 trial to lead to significant improvement in overall survival in late-stage, platinum-resistant non-small cell lung cancer was six years ago, underlining the difficulty in treating this disease,” said William Doyle, Novocure’s Executive Chairman. “We are also pleased by the profound performance of the TTFields together with immunotherapy, which has the potential to meaningfully extend patient survival beyond what was previously possible. I would like to thank our patients and investigators for their courage and dedication in completing LUNAR. And, I would like to thank Novocure’s employees for their unrelenting commitment to patients and their perseverance in propelling Novocure to this major milestone.”

“We are excited about the potential of TTFields to address the unmet medical needs of lung cancer patients around the world. In China, lung cancer is the most common cancer type with approximately 700,000 new NSCLC cases diagnosed each year,” said Dr. Samantha Du, Founder, Chairperson, and CEO of Zai Lab. “We are pleased to contribute and be a part of the LUNAR study and this partnership is yet another great example of how collaboration benefits everyone.”

Novocure plans to release the full results of the LUNAR study at a future medical conference. Novocure expects to file a Premarket Approval application with the U.S. Food and Drug Administration (FDA) in the second half of 2023. Novocure also expects to file for a CE Mark in the European Union concurrently with the FDA submission.

**About LUNAR**
LUNAR is a pivotal study testing the safety and effectiveness of TTFields when used together with immune checkpoint inhibitors or docetaxel (experimental arm) versus immune checkpoint inhibitors or docetaxel alone (control arm) for patients with stage 4 NSCLC who progressed during or after platinum-based therapy. It is estimated that approximately 46,000 patients receive second-line treatment for stage 4 NSCLC each year in the U.S. The primary endpoint is superior overall survival of patients treated with TTFields plus immune checkpoint inhibitors or docetaxel versus immune checkpoint inhibitors or docetaxel alone. The powered secondary endpoints are superior overall survival of patients treated with TTFields plus immune checkpoint inhibitor versus immune checkpoint inhibitor alone (ICI cohort) and superior overall survival of patients treated with TTFields plus docetaxel versus docetaxel alone (docetaxel cohort). TTFields is intended principally for use with other concomitant standard-of-care treatments, and LUNAR was designed to generate data that contemplates multiple outcomes, all of which Novocure believes will be clinically meaningful.

**About Non-Small Cell Lung Cancer in China**
Lung cancer is the most commonly diagnosed cancer type and the leading cause of cancer death in China. There were approximately 815,563 new cases and 714,699 deaths of lung cancer in China in 2020, respectively. NSCLC accounts for approximately 85% of lung cancer, and approximately 70% of NSCLC is locally advanced or metastatic at initial diagnosis. Similar to the global clinical practice, physicians use different combinations of surgery, radiation and pharmacological therapies to treat NSCLC, depending on the stage of the disease. Surgery, which may be curative in a subset of patients, is usually used in early stages of the disease. Since 1991, radiation with a combination of platinum-based chemotherapy drugs has been the first-line standard of care for locally advanced or metastatic NSCLC. Certain immune checkpoint inhibitors have been approved for the first-line treatment of NSCLC and the standard of care in this setting appears to be evolving rapidly. The standard of care for second-line treatment is also evolving and may include platinum-based chemotherapy for patients who received immune checkpoint inhibitors as their first-line regimen, pemetrexed, docetaxel or immune checkpoint inhibitors.

**About Tumor Treating Fields Therapy**
Tumor Treating Fields (TTFields) are electric fields that exert physical forces to kill cancer cells via a variety of mechanisms. TTFields do not significantly affect healthy cells because they have different properties (including division rate, morphology, and electrical properties) than cancer cells. The multiple, distinct mechanisms of TTFields therapy work together to selectively target and kill cancer cells. Due to its multimechanistic actions, TTFields therapy can be added to cancer treatment modalities in approved indications and demonstrates enhanced effects across solid tumor types

when used with chemotherapy, radiotherapy, immune checkpoint inhibition, or PARP inhibition in preclinical models. TTFields therapy provides clinical versatility that has the potential to help address treatment challenges across a range of solid tumors. To learn more about Tumor Treating Fields therapy and its multifaceted effect on cancer cells, visit tumortreatingfields.com.

**About Novocure**
Novocure is a global oncology company working to extend survival in some of the most aggressive forms of cancer through the development and commercialization of its innovative therapy, Tumor Treating Fields. Novocure's commercialized products are approved in certain countries for the treatment of adult patients with glioblastoma and malignant pleural mesothelioma. Novocure has ongoing or completed clinical studies investigating Tumor Treating Fields in brain metastases, gastric cancer, glioblastoma, liver cancer, non-small cell lung cancer, pancreatic cancer and ovarian cancer.
Headquartered in Root, Switzerland and with a growing global footprint, Novocure has regional operating centers in Portsmouth, New Hampshire and Tokyo, as well as a research center in Haifa, Israel. For additional information about the company, please visit Novocure.com and follow @Novocure on LinkedIn and Twitter.

**Novocure Forward-Looking Statements**
In addition to historical facts or statements of current condition, this press release may contain forward-looking statements. Forward-looking statements provide Novocure's current expectations or forecasts of future events. These may include statements regarding anticipated scientific progress on its research programs, clinical study progress, development of potential products, interpretation of clinical results, prospects for regulatory approval, manufacturing development and capabilities, market prospects for its products, coverage, collections from third-party payers and other statements regarding matters that are not historical facts. You may identify some of these forward-looking statements by the use of words in the statements such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe" or other words and terms of similar meaning. Novocure's performance and financial results could differ materially from those reflected in these forward-looking statements due to general financial, economic, environmental, regulatory and political conditions as well as issues arising from the COVID-19 pandemic and other more specific risks and uncertainties facing Novocure such as those set forth in its Annual Report on Form 10-K filed on February 24, 2022, and subsequent filings with the U.S. Securities and Exchange Commission. Given these risks and uncertainties, any or all of these forward-looking statements may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements. Furthermore, Novocure does not intend to update publicly any forward-looking statement, except as required by law. Any forward-looking statements herein speak only as of the date hereof. The Private Securities Litigation Reform Act of 1995 permits this discussion.

**Investors:**
Ingrid Goldberg
investorinfo@novocure.com
610-723-7427

**Media:**
Leigh Labrie
media@novocure.com
610-723-7428

**About Zai Lab**
Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial-stage biopharmaceutical company based in China and the United States focused on bringing transformative medicines for oncology, autoimmune disorders, infectious diseases, and neurological disorders to patients in China and around the world. Our goal is to leverage our competencies and resources to positively impact human health worldwide.

For additional information about Zai Lab, including our products, business activities and partnerships, research, and other events or developments, please visit www.zailaboratory.com and follow us at www.twitter.com/ZaiLab_Global.

**Zai Lab Forward-Looking Statements**
This press release contains forward-looking statements about future expectations, plans, and prospects, including, without limitation, statements relating to Tumor Treating Fields, the LUNAR study, and the potential treatment of patients with non-small cell lung cancer. All statements, other than statements of historical fact, included in this press release are forward-looking statements, and can be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "will," "would," and other similar expressions.
Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not guarantees or assurances of future performance. Forward-looking statements are based on our expectations and assumptions as of the date of this press release and are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. We may not actually achieve the plans, carry out the intentions, or meet the expectations or projections disclosed in our forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results may differ materially from those indicated by forward-looking statements as a result of various important factors, including but not limited to (1) our ability to successfully commercialize and generate revenue from our approved products, (2) our ability to obtain funding for our operations and business initiatives, (3) the results of our clinical and pre-clinical development of our product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates, (5) the effects of the novel coronavirus (COVID-19) pandemic, including any government actions or lockdown measures taken in response, on our business and general economic, regulatory, and political conditions, (6) risks related to doing business in China, and (7) other factors identified in our most recent annual and quarterly reports and in other reports we have filed with the U.S. Securities and Exchange Commission. We anticipate that subsequent events and developments will cause our expectations and assumptions to change, and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

Our SEC filings can be found on our website at www.zailaboratory.com and on the SEC's website at www.sec.gov.

For more information, please contact:

**Investor Relations:** Lina Zhang
+86 136 8257 6943

lina.zhang@zailaboratory.com

**Media:** Christine Drury / Xiaoyu Chen
+1 (317) 385-9227 / +86 185 0015 5011
christine.drury@zailaboratory.com / xiaoyu.chen@zailaboratory.com

Zai Lab Limited



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